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| APPLICATION NO.                    | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|------------------------------------|-------------|----------------------|----------------------|------------------|
| 10/580,447                         | 05/23/2006  | Stuart Greenhalgh    | BD/3-22349/A/PCT     | 4196             |
| 324                                | 7590        | 10/15/2008           | EXAMINER             |                  |
| JoAnn Villamizar                   |             |                      | MACAULEY, SHERIDAN R |                  |
| Ciba Corporation/Patent Department |             |                      | ART UNIT             |                  |
| 540 White Plains Road              |             |                      | PAPER NUMBER         |                  |
| P.O. Box 2005                      |             |                      | 1651                 |                  |
| Tarrytown, NY 10591                |             |                      | MAIL DATE            |                  |
|                                    |             |                      | DELIVERY MODE        |                  |
|                                    |             |                      | 10/15/2008           |                  |
|                                    |             |                      | PAPER                |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/580,447

**Applicant(s)**

GREENHALGH ET AL.

**Examiner**

SHERIDAN R. MACAULEY

**Art Unit**

1651

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

A response and amendment were received and entered on June 9, 2008. All evidence and arguments have been fully considered. Claims 1-12 and 14-18 are pending and examined on the merits in this office action.

#### ***Claim Rejections - 35 USC § 102***

1. Rejections under 35 USC 102 have been withdrawn due to applicant's arguments (par. 1-3 on p. 3 of applicant's arguments filed June 9, 2008).

#### ***Claim Rejections - 35 USC § 102/103***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 14-16 and 18 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yamada et al. (US 5,334,519), when taken in view of Seki et al. (US Pat. 5,352,828). Claim 1 recites a process for preparing a polymer of an ethylenically unsaturated monomer, in which the monomer is obtained from a biocatalysed reaction or fermentation process, and wherein the monomer contains cellular material and/or components of a fermentation process; forming the polymer by polymerizing the ethylenically unsaturated monomer or

monomer mixture comprising the ethylenically unsaturated monomer and cellular material and/or components of a fermentation. Claim 2 recites the process according to claim 1 wherein the ethylenically unsaturated monomer is prepared by providing a substrate that can be converted into an ethylenically unsaturated monomer, contacting the substrate with a biocatalyst which comprises a microorganism or cellular material and thereby converting the substrate into the ethylenically unsaturated monomer containing the cellular material and/or components of a fermentation broth and that this process is carried out inside or outside of an the cell and where it is carried out inside the cell and where it is carried out inside the cell it optionally forms part of the metabolic pathway of the microorganism. Claim 3 recites the process according to claim 2 in which the biocatalyst comprises a microorganism and wherein the process is carried out inside the cell and forms part of a metabolic process of the microorganism. Claim 4 recites the process according to claim 1 in which the cellular material comprises whole cells. Claim 5 recites the process according to claim 1 in which the cellular material comprises fractured cellular material. Claim 6 recites the process according to claim 5 in which the fractured cellular material is selected from the group consisting of cell wall material, cell membrane material, cell nucleus material, cytoplasm and proteins. Claim 7 recites the process according to claim 1 in which the components of the fermentation broth are selected from the group consisting of sugars, polysaccharides, proteins, peptides, amino acids, nitrogen sources, inorganic salts (including metal salts), vitamins, growth regulators, enzyme inducers and complex fermentation medium components. Claim 8 recites the process according to claim 1 in which the ethylenically

Art Unit: 1651

unsaturated monomer is methacrylamide monomer. Claim 9 recites the process according to claim 2 in which the substrate is methacrylonitrile. Claim 10 recites the process according to claim 2 in which the biocatalyst comprises a nitrile hydratase enzyme. Claim 11 recites the process according to claim 1 in which the polymer is a homopolymer or copolymer of methacrylamide. Claim 12 recites the process according to claim 1 in which the ethylenically unsaturated monomer is selected from the group consisting of itaconic acid (or salts thereof), maleic acid (or salts thereof) and methacrylic acid or salts and derivatives thereof. Claim 14 recites the process according to claim 2 in which the substrate is introduced into a vessel and contacted with a biocatalyst and wherein the substrate is converted into the ethylenically unsaturated monomer, optionally introduction other monomers into the vessel to form a monomer mixture, subjecting the ethylenically unsaturated monomer or monomer mixture to polymerization conditions, optionally by introducing initiators into the vessel, and thereby forming the polymer inside the vessel. Claim 15 recites a process according to claim 14 in which the biocatalyst is produced inside the vessel. Claim 16 recites a process according to claim 2 in which the biocatalyst comprises microorganisms of the *Rhodococcus* genus. Claim 18 recites a composition comprising a polymer of an ethylenically unsaturated monomer and further comprising cellular material and/or components of a fermentation broth, wherein the composition is obtained by a process according to claim 1.

3. Yamada teaches a process for preparing an acryamide (an ethylenically unsaturated monomer such as methacrylamide) in which the monomer is obtained from

a biocatalysed reaction or fermentation process wherein the substrate (a nitrile such as methacrylonitrile) is contacted by a biocatalyst which comprises a microorganism or cellular material and thereby converted into the monomer (abstract, col. 12, lines 12-40). In the process of Yamada, after the substrate is converted into a monomer, it contains cellular material and/or components of the fermentation medium, such as complex fermentation components (col. 12, lines 12-40). In the process of Yamada, the cellular material may comprise whole cells or fractured cellular material, such as cell wall material, and the process would inherently occur inside of the cell and form part of a metabolic process (col. 8, lines 1-39). Yamada teaches that the biocatalyst comprises *Rhodococcus rhodochrous*, which comprises nitrile hydratase (abstract). The process of Yamada occurs inside of a bioreactor or vessel (col. 8, lines 21-25, col. 12, lines 12-40).

4. Yamada does not teach the formation of a polymer (homopolymer or copolymer of methacrylamide) in the vessel comprising the ethylenically unsaturated monomer wherein the unsaturated monomer comprises cellular material and/or components of the fermentation broth.

5. Seki teaches that, under most conditions, polymerization of a solution of acrylamide, an ethylenically unsaturated monomer, will occur (col. 2, lines 13-19).

6. At the time of the invention, a process of preparing a monomer comprising nearly all of the claimed elements was known, as taught by Yamada. It was further known that solutions of monomers are likely to polymerize if they are not stabilized. Since the method of Yamada does not explicitly teach stabilizing the fermentation broth against

Art Unit: 1651

polymerization, it is either inherent to the teachings of Yamada, or it would occur during routine optimization and experimentation, that polymerization of the fermentation broth would occur. One of ordinary skill in the art would have a reasonable expectation of success in polymerizing the fermentation broth taught by Yamada because polymerization of acrylamide solutions is known to occur in such solutions spontaneously, as taught by Seki. The spontaneously produced polymer of Yamada would either be a homopolymer or copolymer of methacrylamide. Therefore, Yamada anticipates the cited claims, or, in the alternative, it would have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.



9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-12 and 14-18 stand rejected under 35 U.S.C. 103(a) as obvious over Yamada et al. (US 5,334,519) in view of Seki et al. (US Pat. 5,352,828) and Leonova et al. (Applied Biochemistry and Biotechnology, 2000, 88:231-241, document cited in IDS). Claim 1 recites a process for preparing a polymer of an ethylenically unsaturated monomer, in which the monomer is obtained from a biocatalysed reaction or fermentation process, and wherein the monomer contains cellular material and/or components of a fermentation process; forming the polymer by polymerizing the ethylenically unsaturated monomer or monomer mixture comprising the ethylenically unsaturated monomer and cellular material and/or components of a fermentation. Claim 2 recites the process according to claim 1 wherein the ethylenically unsaturated monomer is prepared by providing a substrate that can be converted into an ethylenically unsaturated monomer, contacting the substrate with a biocatalyst which comprises a microorganism or cellular material and thereby converting the substrate

Art Unit: 1651

into the ethylenically unsaturated monomer containing the cellular material and/or components of a fermentation broth and that this process is carried out inside or outside of an the cell and where it is carried out inside the cell and where it is carried out inside the cell it optionally forms part of the metabolic pathway of the microorganism. Claim 3 recites the process according to claim 2 in which the biocatalyst comprises a microorganism and wherein the process is carried out inside the cell and forms part of a metabolic process of the microorganism. Claim 4 recites the process according to claim 1 in which the cellular material comprises whole cells. Claim 5 recites the process according to claim 1 in which the cellular material comprises fractured cellular material. Claim 6 recites the process according to claim 5 in which the fractured cellular material is selected from the group consisting of cell wall material, cell membrane material, cell nucleus material, cytoplasm and proteins. Claim 7 recites the process according to claim 1 in which the components of the fermentation broth are selected from the group consisting of sugars, polysaccharides, proteins, peptides, amino acids, nitrogen sources, inorganic salts (including metal salts), vitamins, growth regulators, enzyme inducers and complex fermentation medium components. Claim 8 recites the process according to claim 1 in which the ethylenically unsaturated monomer is methacrylamide monomer. Claim 9 recites the process according to claim 2 in which the substrate is methacrylonitrile. Claim 10 recites the process according to claim 2 in which the biocatalyst comprises a nitrile hydratase enzyme. Claim 11 recites the process according to claim 1 in which the polymer is a homopolymer or copolymer of methacrylamide. Claim 12 recites the process according to claim 1 in which the

ethylenically unsaturated monomer is selected from the group consisting of itaconic acid (or salts thereof), maleic acid (or salts thereof) and methacrylic acid or salts and derivatives thereof. Claim 14 recites the process according to claim 2 in which the substrate is introduced into a vessel and contacted with a biocatalyst and wherein the substrate is converted into the ethylenically unsaturated monomer, optionally introduction other monomers into the vessel to form a monomer mixture, subjecting the ethylenically unsaturated monomer or monomer mixture to polymerization conditions, optionally by introducing initiators into the vessel, and thereby forming the polymer inside the vessel. Claim 15 recites a process according to claim 14 in which the biocatalyst is produced inside the vessel. Claim 16 recites a process according to claim 2 in which the biocatalyst comprises microorganisms of the *Rhodococcus* genus. Claim 17 recites the process of claim 16 wherein the microorganism is *Rhodococcus rhodochrous* NCIMB 41164. Claim 18 recites a composition comprising a polymer of an ethylenically unsaturated monomer and further comprising cellular material and/or components of a fermentation broth, wherein the composition is obtained by a process according to claim 1.

11. Yamada teaches a process for preparing an acryamide (an ethylenically unsaturated monomer such as methacrylamide) in which the monomer is obtained from a biocatalysed reaction or fermentation process wherein the substrate (a nitrile such as methacrylonitrile) is contacted by a biocatalyst which comprises a microorganism or cellular material and thereby converted into the monomer (abstract, col. 12, lines 12-40). In the process of Yamada, after the substrate is converted into a monomer, it

contains cellular material and/or components of the fermentation medium, such as complex fermentation components (col. 12, lines 12-40). In the process of Yamada, the cellular material may comprise whole cells or fractured cellular material, such as cell wall material, and the process would inherently occur inside of the cell and form part of a metabolic process (col. 8, lines 1-39). Yamada teaches that the biocatalyst comprises *Rhodococcus rhodochrous*, which comprises nitrile hydratase (abstract). The process of Yamada occurs inside of a bioreactor or vessel (col. 8, lines 21-25, col. 12, lines 12-40).

12. Yamada does not teach the formation of a polymer (homopolymer or copolymer of methacrylamide) in the vessel comprising the ethylenically unsaturated monomer wherein the unsaturated monomer comprises cellular material and/or components of the fermentation broth. Yamada does not specifically teach the use of *Rhodococcus rhodochrous* NCIMB 41164 as the biocatalyst.

13. Seki teaches that, under most conditions, polymerization of a solution of acrylamide, an ethylenically unsaturated monomer, will occur (col. 2, lines 13-19).

14. Leonova teaches the production of nitrile hydratase, the enzyme which converts a nitrile to an amide and which is recited in the instant claims, by the organism *Rhodococcus rhodochrous* M8.

15. At the time of the invention, a process of preparing a monomer comprising nearly all of the claimed elements was known, as taught by Yamada. It was further known that solutions of monomers are likely to polymerize if they are not stabilized, as taught by Seki. Since the method of Yamada does not explicitly teach stabilizing the fermentation

Art Unit: 1651

broth against polymerization, it is either inherent to the teachings of Yamada, or it would occur during routine optimization and experimentation, that polymerization of the fermentation broth would occur. One of ordinary skill in the art would have a reasonable expectation of success in polymerizing the fermentation broth taught by Yamada because polymerization of acrylamide solutions is known to occur in such solutions spontaneously, as taught by Seki. The spontaneously produced polymer of Yamada would either be a homopolymer or copolymer of methacrylamide. Furthermore, although none of the references specifically disclose the use of the claimed strain in the method for the production of polymers, the microbial species *Rhodococcus rhodochrous* was known in the time of the art to perform the biocatalytic reaction recited in the claims. The selection of a strain of a known organism for use in a known method would have been a matter of routine experimentation to one of ordinary skill in the art. One of ordinary skill in the art would have had a reasonable expectation of success in using a strain of *Rhodococcus rhodochrous* in the claimed method because members of the species were known at the time of the invention to be useful for the production of the monomers recited in the claims. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

16. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

***Response to Arguments***

17. Applicant's arguments filed June 9, 2008 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated by or obvious over Yamada, when taken in view of Seki, because Yamada does not teach polymerization in the presence of cellular material and teaches away from polymerization in the presence of iron.

18. In response to applicant's argument that the claims are not anticipated by or obvious over Yamada, when taken in view of Seki, because Yamada does not teach polymerization in the presence of cellular material, it is noted that in Example 4 (col. 12) of Yamada, the reference discloses reacting the bacterial cells in the presence of methacrylonitrile for 12 hours before any removal of cellular material from the reaction mixture. As discussed above, Seki teaches spontaneous polymerization of acrylamide solutions under various conditions. Thus, the solution of Yamada would inherently have polymerized to some extent during the incubation period. In the alternative, it would have been a matter of routine experimentation for one of ordinary skill in the art to have incubated the solution of Yamada under conditions that would have resulted in the spontaneous polymerization described by Seki. Although applicant argues that Yamada teaches away from exposure of the reaction mixture to iron, which applicant argues would have been necessary for the polymerization of the solution, Seki does not teach that such conditions are required for polymerization of the solution. For example, Seki discloses at col. 1, lines 45-50 that acrylamide solutions may polymerize by exposure to light or heat as well. Thus, many conditions, including those disclosed in Yamada,

could have resulted in the polymerization of the solution in the presence of cellular material. Applicant's argument is therefore not found to be persuasive.

19. Thus applicant's arguments have been fully considered, but they have not been found to be persuasive.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **SHERIDAN R. MACAULEY** whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

Art Unit: 1651

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/  
Primary Examiner, Art Unit 1651